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Susan Mosier, MD, Acting Secretary

Department of Health & Environment

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
January 14, 2015 10am – 2pm

Meeting Location
HP Enterprise Services, Capital Room
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619

Board Members

James Backes, PharmD
Tim Heston, DO
John Kollhoff, PharmD
Judy McDaniel Dowd, PA-C
Russell Scheffer, MD
Kevin Waite, PharmD
Roger Unruh, DO

KDHE-DHCF Staff

Liane Larson, PharmD
Kelley Melton, PharmD

HP Enterprise Services/HID Staff

Nicole Ellermeier, PharmD
Karen Kluczykowski, RPh
Nancy Perry, RN

MCO Staff

Jonalan Smith, PharmD, FASCP, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of October 8, 2014 and November 14, 2014 Meeting Minutes

III. NEW BUSINESS

A. Revised Prior Authorization (PA) Criteria

1. **Harvoni® (ledipasvir/sofosbuvir)**
   Prior authorization criteria for Harvoni was approved in November 2014, and at that time, a renewal timeline for treatment-naïve patients with cirrhosis was inadvertently left off of the criteria. The criteria is being revised to include renewals for treatment-naïve patients with cirrhosis for 12 weeks of total therapy with Harvoni.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Humira® (adalimumab)**
   Prior authorization criteria for Humira was last revised in April 2013, and since that time, the indication for Juvenile Idiopathic Arthritis (JIA) has been reduced from patients 4 years of age and older to 2 years of age and older and there has been an expansion to include pediatric Crohn's disease. The prior authorization criteria is being revised to include the current FDA-approved indications.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Interferons for Multiple Sclerosis (Plegridy™ [interferon beta-1a])**
   The prior authorization criteria for interferons for multiple sclerosis was initially approved in October 2012, and since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Plegridy.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Otezla® (apremilast)**
   Prior authorization criteria for Otezla was initially approved in July 2014, and since that time, a new indication has been approved. Otezla is now approved for use in patients with moderate to severe plaque psoriasis. The prior authorization criteria is being revised to include this new indication.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Methotrexate Subcutaneous Injections (Rasuvo™ [methotrexate])**
   Prior authorization criteria for Otrexup™ (methotrexate subcutaneous injection) was initially approved in January 2014, and since that time, a new agent has been approved. Prior authorization criteria revisions are being proposed to include Rasuvo.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Opioid Induced Constipation Agents (Relistor® [methylnaltrexone] & Movantik™ [naloxegol])**
   Prior authorization criteria for Relistor was initially approved in September 2008. Since that time, Relistor was approved for a new indication and a new agent was approved. The prior authorization criteria is being revised to include the new indication for Relistor and the new agent, Movantik.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Weight Loss Drugs (Contrave ER® [naltrexone/bupropion])**
   Prior authorization criteria for the weight loss agents was brought before the DUR board in April 2014, and since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Contrave ER.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Long-Acting Opioids (Butrans® [buprenorphine patch], Targiniq™ ER [oxycodone/naloxone] & Hysingla™ ER [hydrocodone])**
   Limitations and override criteria for the long-acting opioids was last revised in July 2014, and since that time, two new agents have been approved by the FDA. In addition to the new agents, a new strength of Butrans has been approved and is being added to the limitations for long-acting opioids. Limitations are being proposed for the new agents and the override criteria is being revised to include both Targiniq ER and Hysingla ER.
   i. Revised Override Criteria
   ii. *Public Comment
   iii. Board Discussion

B. New PA Criteria

1. **Viekira Pak™ (ombitasvir/paritaprevir/ritonavir & dasabuvir co-packaged)**
   Viekira Pak is a recently approved chronic hepatitis C medication. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Lemtrada™ (alemtuzumab)**
   Lemtrada is a monoclonal antibody indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Trulicity™ (dulaglutide)**
   Trulicity is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents in this class.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Hetlioz® (tasimelteon)**
   Hetlioz is a melatonin receptor antagonist indicated for the treatment of non-24-hour sleep-wake disorder (non-24). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Idiopathic Pulmonary Fibrosis Treatments (Esbriet® [pirfenidone] & Ofev® [nintedanib])**
   Esbriet is a pyridone and Ofev is a kinase inhibitor; both are indicated for the treatment of idiopathic pulmonary fibrosis. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Banzel® (rufinamide)**
   Banzel is an anti-epileptic drug indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 4 years of age and older. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Sabril® (vigabatrin)**
   Sabril is an anti-epileptic drug indicated for adjunctive treatment of refractory complex partial seizures and infantile spasms. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Onfi® (clobazam)**
   Onfi is an anti-epileptic drug indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older. In April 2012, the DUR board approved diagnosis restrictions for Onfi, but since that time, utilization has increased. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for April 8, 2015.

[Click Here To Begin]

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion.
Informal comments will be accepted from members of the audience at various points in the agenda.
****THIS AGENDA IS SUBJECT TO CHANGE****